

We claim:

- 1 1. Highly pure cefditoren pivoxil, wherein the cefditoren pivoxil has a purity greater  
2 than 98.5% and contains less than 1.0% of E-isomer impurity and less than 1% of  
3  $\Delta^2$ -isomer impurity.
- 1 2. The compound according to claim 1, wherein the compound is in an amorphous  
2 form.
- 1 3. The compound according to claim 2, wherein the compound has a XRD pattern as  
2 depicted in Figure I.
- 1 4. The compound according to claim 1, wherein the compound is in a crystalline  
2 form.
- 1 5. The compound of claim 4, wherein the compound has a XRD pattern as depicted in  
2 Figure II.
- 1 6. A process for preparing crystalline cefditoren pivoxil from amorphous cefditoren  
2 pivoxil, the process comprising:
  - 3 a) (i) adding amorphous cefditoren pivoxil to an organic solvent optionally  
4 containing water and/or (ii) adding an organic solvent optionally containing  
5 water to amorphous cefditoren pivoxil;
  - 6 b) crystallizing the product from the reaction mixture; and
  - 7 c) isolating crystalline cefditoren pivoxil.
- 1 7. The process according to claim 6, wherein the organic solvent is one or more of an  
2 alcohol, a ketone, an ester, a cyclic ether, a nitrile, a glycol, a chlorinated  
3 hydrocarbon, or a mixture thereof.
- 1 8. The process according to claim 7, wherein the alcohol is one or more of ethanol,  
2 methanol, isopropyl alcohol, n-butanol, iso-butanol, amyl alcohol or a mixture  
3 thereof.
- 1 9. The process according to claim 7, wherein the ester is one or more of ethyl  
2 formate, methyl acetate, ethyl acetate, isobutyl acetate, butyl acetate or a mixture  
3 thereof.

- 1 10. The process according to claim 7, wherein the ketone is one or more of acetone,  
2 methyl ethyl ketone, diisobutyl ketone, methyl isobutyl ketone or a mixture  
3 thereof.
- 1 11. The process according to claim 7, wherein the cyclic ether is one or more of  
2 tetrahydrofuran, 1,4-dioxane or a mixture thereof.
- 1 12. The process according to claim 7, wherein the glycol is one or more of propylene  
2 glycol, ethylene glycol or a mixture thereof.
- 1 13. The process according to claim 7, wherein the chlorinated hydrocarbon is one or  
2 more of methylene chloride, ethylene chloride, chloroform or a mixture thereof.
- 1 14. The process according to claim 7, wherein the organic solvent contains about 0.01  
2 to about 50% by weight of water.
- 1 15. The process according to claim 6, wherein the reaction mixture is stirred at a  
2 temperature of about -20°C to about 100°C to crystallize.
- 1 16. The process according to claim 6, wherein the crystallization temperature is kept in  
2 the range of about 0°C to about 60°C.
- 1 17. The process according to claim 6, wherein the cefditoren pivoxil obtained is highly  
2 pure cefditoren pivoxil having a purity greater than 98.5%, the E-isomer is less  
3 than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
- 1 18. A process for preparing an amorphous form cefditoren pivoxil from crystalline  
2 cefditoren pivoxil, the process comprising:
  - 3 a) dissolving crystalline cefditoren pivoxil in a first organic solvent;
  - 4 b) adding a second organic solvent to the solution or adding the solution to the  
5 second organic solvent in optional order of succession to precipitate  
6 cefditoren pivoxil; and
  - 7 c) isolating the amorphous cefditoren pivoxil from the reaction mixture.
- 1 19. The process according to claim 18, wherein the first organic solvent is at least one  
2 water-immiscible or partially miscible solvent.

- 1 20. The process according to claim 19, wherein the at least one water-immiscible or  
2 partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated  
3 hydrocarbon or a mixture thereof.
- 1 21. The process according to claim 18, wherein the second organic solvent is an alkyl  
2 ether, a hydrocarbon or a mixture thereof.
- 1 22. The process according to claim 18, wherein the cefditoren pivoxil obtained is  
2 highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is  
3 less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
- 1 23. The process according to claim 18, wherein the dissolution of crystalline cefditoren  
2 pivoxil in the first organic solvent is effected by initially dissolving crystalline  
3 cefditoren pivoxil in a third organic solvent.
- 1 24. The process according to claim 23, wherein the third organic solvent is one or  
2 more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane,  
3 methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.
- 1 25. A process for preparing an amorphous form of cefditoren pivoxil, the process  
2 comprising the steps of:
  - 3 a) dissolving crystalline cefditoren pivoxil in a first organic solvent;
  - 4 b) removing the first organic solvent from the reaction mixture; and
  - 5 c) isolating the amorphous form of cefditoren pivoxil.
- 1 26. The process according to claim 25, wherein the first organic solvent is at least one  
2 water-immiscible or partially miscible solvent.
- 1 27. The process according to claim 26, wherein the at least one water-immiscible or  
2 partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated  
3 hydrocarbon or a mixture thereof.
- 1 28. The process according to claim 26, further comprising applying heat to dissolve the  
2 crystalline form in the first organic solvent.
- 1 29. The process according to claim 26, wherein the first organic solvent is removed  
2 under reduced pressure.

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- 1 30. The process according to claim 26, wherein the first organic solvent is removed by  
2 spray-drying the solution of crystalline cefditoren pivoxil.
- 1 31. The process according to claim 25, wherein the cefditoren pivoxil obtained is  
2 highly pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is  
3 less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
- 1 32. A process for preparing a highly pure amorphous form of cefditoren pivoxil from  
2 crystalline form which comprises the steps of:
  - 3 a) dissolving a crystalline form of cefditoren pivoxil in an organic solvent  
4 optionally containing water; and
  - 5 b) freeze drying or lyophilizing the solution to get highly pure amorphous  
6 form of cefditoren pivoxil, wherein the cefditoren pivoxil obtained is highly  
7 pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is  
8 less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
- 1 33. The process according to claim 32, wherein the organic solvent comprises at least  
2 one water-immiscible or partially miscible solvent.
- 1 34. The process according to claim 33, wherein the at least one water-immiscible or  
2 partially miscible solvent is an alcohol, a ketone, an ester, a chlorinated  
3 hydrocarbon or a mixture thereof.
- 1 35. The process according to claim 32, further comprising applying heating to dissolve  
2 the crystalline form in the organic solvent.
- 1 36. A process for preparing a highly pure amorphous form of cefditoren pivoxil from  
2 crystalline form, the process comprising the steps of:
  - 3 a) dissolving the crystalline cefditoren pivoxil in an acid, optionally in the  
4 presence of a water miscible organic solvent;
  - 5 b) adding water to the solution in an amount sufficient to precipitate the  
6 cefditoren pivoxil from the solution; and
  - 7 c) isolating the highly pure amorphous cefditoren pivoxil from the solution,  
8 wherein the cefditoren pivoxil obtained is highly pure cefditoren pivoxil and has a

9       purity greater than 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer  
10      impurity is less than 1%.

1    37. The process according to claim 36, wherein the acid is at least one of an organic  
2    acid or an inorganic acid.

1    38. The process according to claim 37, wherein the organic acid is one or more of C<sub>1-12</sub>  
2    alkyl or aryl carboxylic acids, C<sub>1-10</sub> alkyl or aryl sulphonic acids or a mixture  
3    thereof.

1    39. The process according to claim 38, wherein the C<sub>1-10</sub> alkyl or aryl carboxylic acid  
2    is one or more of formic acid, acetic acid, propionic acid, butyric acid, acrylic acid,  
3    benzoic acid, mono-, di- or trisubstituted benzoic acids, phenyl acetic acid,  
4    substituted phenyl acetic acid or a mixture thereof.

1    40. The process according to claim 38, wherein the C<sub>1-12</sub> alkyl or aryl sulphonic acid is  
2    one or more of methanesulphonic acid, p-toluenesulphonic acid, benzenesulphonic  
3    acid or a mixture thereof.

1    41. The process according to claim 37, wherein inorganic acid is one or more of  
2    hydrochloric acid, nitric acid, sulphuric acid, phosphoric acid or a mixture thereof.

1    42. The process according to claim 36, wherein the acid contains a water miscible  
2    organic solvent.

1    43. The process according to claim 42, wherein water miscible organic solvent is one  
2    or more of dimethylformamide, dimethylacetamide, tetrahydrofuran, 1,4-dioxane,  
3    methanol, acetone, acetonitrile, ethanol, isopropanol or a mixture thereof.

1    44. A process for converting a mixture of the amorphous and crystalline forms of  
2    cefditoren pivoxil to highly pure amorphous form of cefditoren pivoxil, wherein  
3    the mixture of amorphous and crystalline form of cefditoren pivoxil is prepared  
4    directly from the reaction mixture, from the crystalline form or from the  
5    amorphous form of cefditoren pivoxil and the cefditoren pivoxil obtained is highly  
6    pure cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less  
7    than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.

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- 1 45. A pharmaceutical composition comprising a highly pure amorphous or crystalline
- 2 form of cefditoren pivoxil and a pharmaceutically acceptable carrier, wherein the
- 3 cefditoren pivoxil is highly pure cefditoren pivoxil and has a purity greater than
- 4 98.5%, the E-isomer is less than 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.
- 1 46. A method of treating infections caused by gram positive, gram negative and
- 2 resistant strains of bacteria comprising administering to a mammalian host in need
- 3 thereof a therapeutically effective amount of the highly pure amorphous or
- 4 crystalline form of cefditoren pivoxil, wherein the cefditoren pivoxil is highly pure
- 5 cefditoren pivoxil and has a purity greater than 98.5%, the E-isomer is less than
- 6 1.0% and the  $\Delta^2$ -isomer impurity is less than 1%.